

# New Therapeutic Technique for Treatment of Uterine Leiomyomas Using Laser-Induced Interstitial Thermotherapy (LITT) by a Minimally Invasive Method

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**Background and Objective:** This study was undertaken to see if uterine leiomyomas would respond to LITT, as had certain other tumours, and leave behind a uterus capable of child bearing.

**Study Design/Materials and Methods:** Preliminary research to determine laser power and energy requirements to coagulate leiomyomas was carried out on such tumours at the time of myomectomy or hysterectomy. The information gleaned permitted subsequent volunteer patients to be treated by a minimally invasive route. LITT was employed to treat 300 patients, 293 of them with the KTP/YAG laser with a bare fibre laparoscopically or through the hysteroscope. The remaining seven were treated with the Diode laser, five of them being treated percutaneously with fibre splitter and four fibres.

**Results:** Symptomatic patients (300) with 950 myomas between them were treated. Follow-up has been between 6 months and 6 years. No significant complications occurred, and the procedure(s) were successful in 294 patients.

**Conclusions:** It is the treatment of choice for those leiomyomas that are difficult to remove because of their size or position. Fertility is enhanced, oestrogen receptors and epidermal growth factor are destroyed, and healing occurs without scarring. *Lasers Surg. Med.* 22:171-178, 1998. © 1998 Wiley-Liss, Inc.

**Key words:** laser-induced interstitial thermotherapy; KTP/YAG laser; diode laser; oestrogen receptors; epidermal growth factor

## INTRODUCTION

Humans have long been concerned with fertility; compare the fertility lime stone statuette known as the Venus of Willendorf (c. 30,000 BC) [1] with a modern in vitro fertilization department. To preserve fertility, Amussat in 1840 for the first time treated a uterine leiomyoma by myomectomy [2]. More than 150 years later, women expect better treatment than a major operation with, often, the loss of the whole organ.

Uterine leiomyomas, the commonest of pelvic tumours, arise in the myometrium and are oestrogen dependent [3]. They are frequently multiple and during the period of reproductive life, they can grow enormously. Growth is also likely to occur postmenopausally if hormone replace-

ment therapy (HRT) is given [4]. Because myomectomy is a hazardous procedure, it has tended to be reserved for symptomatic patients, or for instances when the uterus is enlarged by the myomas to a size greater than that of a 12-week gestation if infertility is a problem. Otherwise, hysterectomy is the preferred method of management. Myomectomy is usually followed by dense intraperitoneal adhesions, thus making future pregnancy uncertain and subsequent hysterectomy even more risky, and although a microsurgical

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Fig. 1. Leiomyoma being treated simultaneously with a bare fibre and diffuser fibre prior to hysterectomy.

gical technique has been employed for myomectomy and has claimed a significantly improved pregnancy rate [5], adhesion formation still occurs.

In 1989, Steger et al.[6] described the treatment of five patients with malignant tumours of different organs by low power laser-induced interstitial thermotherapy (LITT). Although the treatment was palliative, it was noted that the tumours shrank and some ceased to grow again. This form of treatment was first employed in 1983 [7] and has been used mainly in life-threatening conditions for the treatment of deep-seated malignancies or for palliation. The author also has used this form of low-power LITT for the treatment of uterine leiomyomas [8–13]. High-power laser also has been employed [14–18], but necrosis and sloughing occur, the quartz fibre tip may break, and adhesion formation at the site of treatment is the rule, thus rendering the uterus unsuitable for future child bearing.

## MATERIALS AND METHODS

Uterine leiomyomas are unique to homo sapiens; therefore preliminary laser research was carried out on leiomyomas of patients who were

undergoing hysterectomy or myomectomy at the time of operation to determine the appropriate power and energy required for LITT (Fig. 1). All patients treated had symptomatic leiomyomas, had been assessed elsewhere, 270 (90%) with curettage and laparoscopy, and had been offered hysterectomy. This had been refused as a first option, and they were therefore referred for a second opinion.

Laser-induced interstitial thermotherapy, or LITT, was explained and informed consent was given. The uterine size varied from that of a bulky uterus to that of a full-term pregnancy. All leiomyomas that could not be removed surgically at laparoscopy and hysteroscopy or at laparotomy were treated by this new modality.

Pre-operative GnRH analogue was given, preferably for 3 months, but, in those from overseas, often for only 6 weeks, in order to shrink the tumour before the operation [19]. This also allowed some large leiomyomas to be treated laparoscopically when otherwise this would not have been possible. Unfortunately, it had the disadvantage of masking the presence of small myomas and of certain other diseases, in particular, adenomyosis and endometriosis.

All patients were assessed bimanually, by ul-

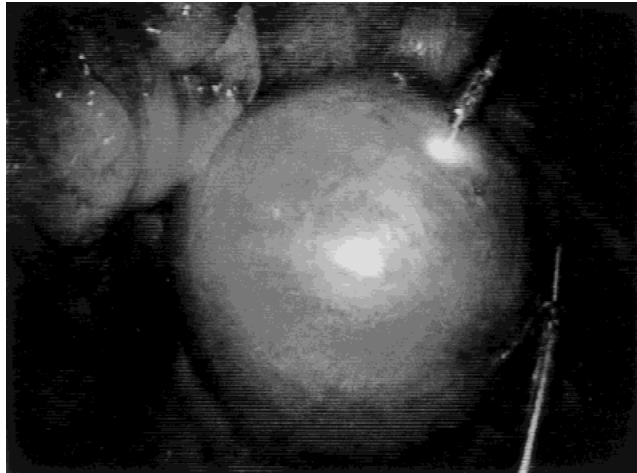
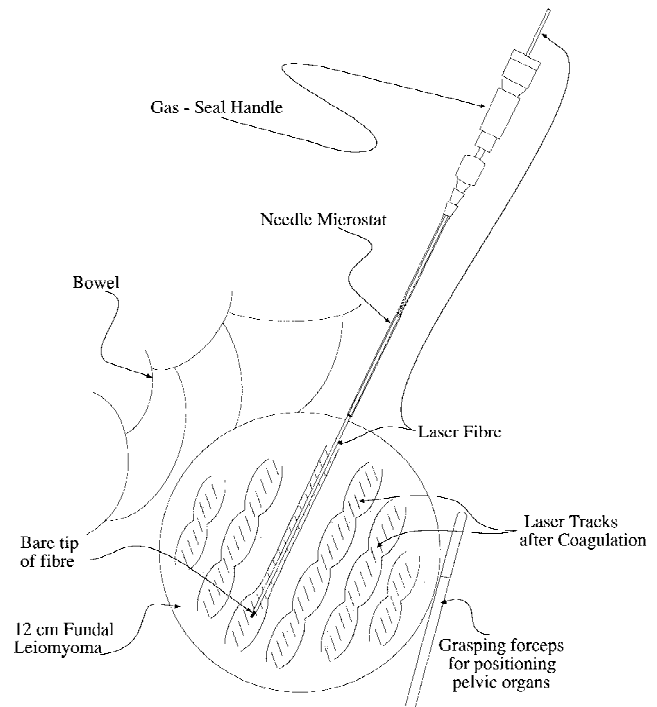


Fig. 2. Laparoscopic laser treatment of 12 cm diameter leiomyoma in which access for the 1,000  $\mu\text{m}$  quartz laser fibre is gained through the irrigation-aspiration cannula. Diagram showing how the laser fibre is inserted in the myoma at the time of laparoscopy (for simplicity the fibre is shown passing through a needle microstat rather than the irrigation-aspiration cannula).



trasound and occasionally by computed tomography (CT) or magnetic resonance imaging (MRI), before and at monthly intervals during preliminary medical treatment. Ultrasound was also used to measure the number and diameter of the myomas prior to operation. Tru-cut biopsies were taken at the time of laparoscopy, prior to laser treatment, to confirm the diagnosis histologically and, in the rare case when shrinkage did not occur, to exclude malignancy [20, 21].

A total of 293 (98%) patients were treated laparoscopically under general anaesthesia with a Potassium-Titanyl-Phosphate/Neodymium:Yttrium-Aluminium-Garnet (KTP/YAG) laser of 532 nm and 1064 nm wavelengths, respectively. The needle microstat, a long thin cannula consisting of a 15-gauge sheath with a locking stilette and gas-seal handle, was inserted through the anterior abdominal wall, into the peritoneal cavity to allow access of the 600  $\mu\text{m}$  quartz laser fibre with a bare tip, which was normally used for treatment. However, latterly the 1,000  $\mu\text{m}$  quartz laser fibre was more often used because the bare quartz tip was less liable to break and, in these cases, intraperitoneal access was gained through the irrigation-aspiration cannula (Fig. 2). Hysteroscopy was always performed immediately before laparoscopy and any submucous leiomyomas or interstitial myomas encroaching upon the uterine cavity were treated by laser through the hysteroscope.

After completion of hysteroscopy, an intra-uterine cannula was inserted to enable the uterus and appendages to be manipulated and positioned appropriately. A pneumoperitoneum of carbon dioxide gas was then obtained and the laparoscope introduced. The needle microstat was next inserted and the quartz laser fibre was fed through it and was used to measure the diameter of the leiomyoma. This was accomplished by placing the end of the needle microstat at one side of the myoma, advancing the laser fibre external to the tumour to the other side and then withdrawing it and measuring the length with a ruler, due allowance being made for the thickness of the overlying myometrium and false capsule. As explained elsewhere [9], this was often larger than the measurement obtained by previous ultrasound.

With the needle microstat positioned on the surface of the leiomyoma, the KTP component of the laser was switched on and, employing 8 W of power in continuous mode, the bare tip of the laser fibre was advanced through the substance of the myoma to within ~1 cm of the false capsule on its distal side. The YAG component was then utilised at 8 W to coagulate the myoma tissue and the fibre was left in position for 5 minutes and then, depending on the size of the myoma, withdrawn 2 cm and the sequence repeated, and so on until a column of coagulated myoma had been achieved, care being taken as far as possible to

avoid damage to the proximal false capsule (Fig. 2). By this procedure, the KTP component with its ability to vaporize tissue cut swiftly through the leiomyoma, and since it is absorbed by red pigment, it was absorbed by the surrounding red blood cells and coagulated the adjacent blood vessels. The YAG component, however, produced protein denaturation within the cells of the myoma for a radius of ~1 cm from the borehole. Further holes were then drilled at a distance of 2 cm from the original one and the process repeated until the whole leiomyoma had been treated (Fig. 2). The energy (Joules) required depended on the volume of the leiomyoma treated. In practice it varied between 480 J and 20,000 J.

This form of treatment was extremely time-consuming. However, it had already been noticed that the KTP component coagulated the surrounding blood vessels to a distance and angiography in an animal model had shown that the heat damaged the blood vessel endothelium, which resulted in clotting, embolus formation, and slow death of tissue due to anoxia [22]. The procedure was therefore modified and the length of time employed reduced from 5 min to 60 s. This had the effect of producing an area of coagulation 4 mm in diameter. Thus between adjacent boreholes there would be an initial strip of healthy myoma left untreated. However, over the course of the following 6 months, this healthy zone would slowly die and be absorbed so that, at the end, the results of treatment by the two methods were identical. Therefore, 240 (80%) patients were treated by this modified method. This included 18 (6%) patients with sessile myomas in whom the boreholes were mainly directed toward the base where the main blood vessels were to be found. In the procedures described, Tru-cut biopsies were taken at the time of treatment, postoperatively, and at the time of second-look laparoscopy for histological assessment and for the study of oestrogen receptors and the epidermal growth factor.

Approximately 694 leiomyomas (73%) varied between 3 cm and 6 cm in diameter and a single course of LITT was found to make them disappear within 6 months. Of larger size were 237 (25%) leiomyomas, and further LITT was carried out. However, when the uterus was enlarged by leiomyomas to a size greater than that of an 18-week pregnancy, the laparoscope could not be safely used and, in any case, the sheer volume of tumour made the technique unsuitable. This led to the development of a very small pilot study reported

in the BIOS Symposium in San Jose, in 1977, in which five patients with very large leiomyomas were treated percutaneously under local anaesthesia with the Diode laser of 25W and 810 nm wave length employing fibre splitter and multiple fibres with ultrasound and computed tomography (CT) control (Fig. 3). The conclusion was that such treatment was technically possible [12].

Submucous leiomyomas, of which there were 48 in the 300 cases reported, nearly always caused symptoms. They were usually excised with the KTP laser through the hysteroscope and have not been included. Treatment of an intramural leiomyoma encroaching upon the uterine cavity was less simple. If a patient had completed her family, the easier method was to vaporize the bulging myoma together with the overlying endometrium and then apply LITT laparoscopically to the same myoma. This usually cured her symptoms, but she might develop intrauterine adhesions. If, however, she desired further children, holes were drilled in the bulging myoma and the endometrium was preserved. Obviously, the laser fibre could be inserted only a very short distance for one did not know what lay beyond. Nevertheless, this proved to be highly effective, and pregnancies have subsequently occurred without complication.

## RESULTS

Ninety-two patients (30%) treated were English; the others came from all parts of the world, including 149 (50%) from Africa and the Indian subcontinent. Their ages ranged from 23–60 with most in the 40–50 age group. Forty five (16%) were postmenopausal and had heavy bleeding in association with HRT.

Gravidity ranged from 0–14 with the largest number having between two and five children. However, 60 (20%) were nulliparous or had only had miscarriages or terminations of pregnancy.

The symptoms that necessitated consultant referral usually included some form of menstrual abnormality and often abdominal pain. A breakdown is contained in Table 1, which also notes the improvement of symptomatology following treatment.

By no means were all nulliparous patients concerned with fertility. Nevertheless, 51 (17% of the total number of patients) complained of infertility. Of these, 35 (90%), in whom the only pathology was leiomyoma, became pregnant after



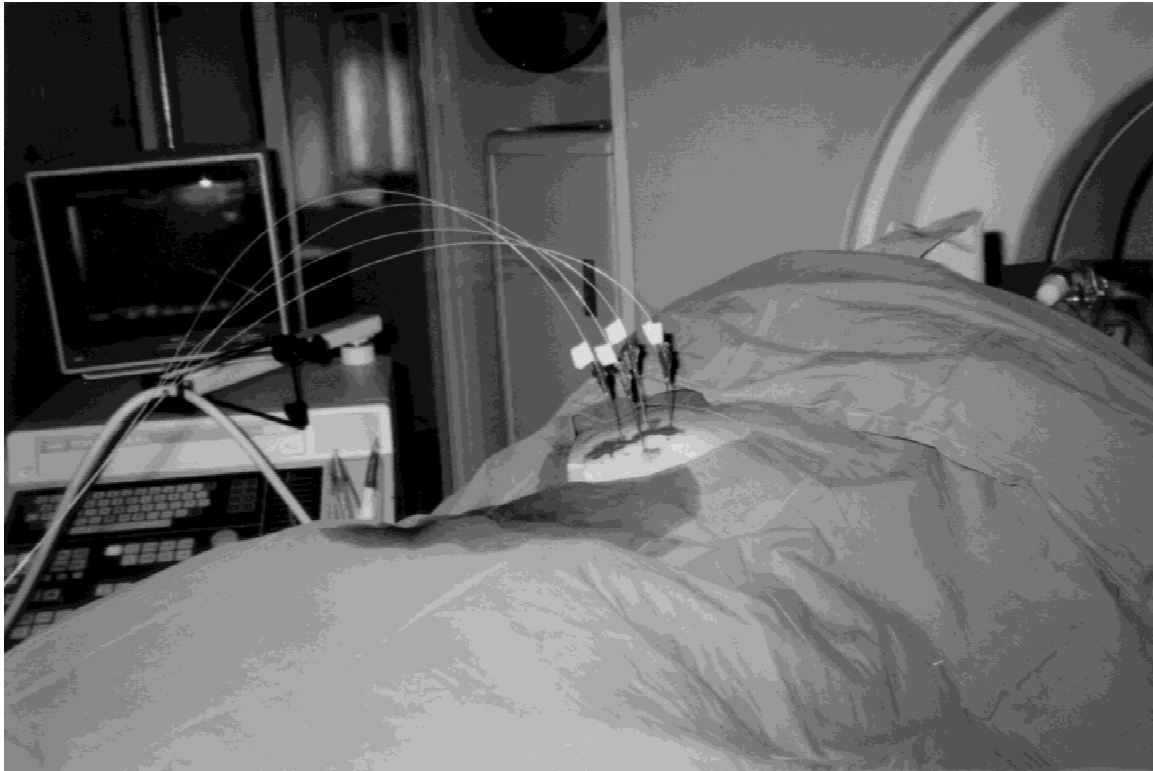


Fig. 3. Patient with needles and laser fibres inserted percutaneously. The ultrasound and computed tomography machines are in evidence.

**TABLE 1. Preoperative Symptomatology and Results Following Treatment**

Symptoms	Preoperative		Postoperative	
	no.	%	no.	%
Mennorrhagia, epimenorrhagia, irregular bleeding, or spotting	276	92%	30 <sup>a</sup>	10% <sup>a</sup>
Low abdominal pain, or dysmenorrhoea	156	52%	24	8%
Dyspareunia	12	4%	0	0%
Frequency or feeling of bladder discomfort	24	8%	0 <sup>b</sup>	0% <sup>b</sup>

<sup>a</sup>Thirty patients (10%) reduced to 3 patients (1%) after second LITT.

<sup>b</sup>Two patients (1%) with low anterior myomas developed a sensation of bladder pressured for the first time immediately after LITT. The symptoms disappeared after 3 weeks.

treatment. However, a number of them had other pathology as well and here, obviously, the incidence of subsequent pregnancy was much less. Seventy-one (24%) of patients referred had previously been treated by myomectomy and had subsequently grown further myomas. Four were referred by in vitro fertilisation (IVF) departments

for the treatment of myomas prior to assisted conception. It is not without interest to note that two patients subsequently became pregnant before IVF was attempted.

Preoperative ultrasound usually confirmed the uterine size as detected by bimanual examination, but correlation between the number of leiomyomas reported by ultrasound and subsequently found at laparoscopy was poor. Usually the number of myomas discovered at laparoscopy were more and their size slightly larger.

Five Caesarean sections are known to have been subsequently performed, two by the author and three elsewhere. There has been no report of wound dehiscence and no scars or adhesions were noted.

Six hysterectomies were subsequently performed in this series and the histological findings are of interest. In two of them unrecognised adenomyosis was found to be the cause of recurrent symptoms. In two others new myomas had grown, but as the patients lived abroad they preferred to have hysterectomy rather than further LITT. In one case endometrial biopsy suggested malignancy, but subsequent hysterectomy revealed the

patient to have a benign endometrial polyp. The final patient had an ectopic kidney. The initial treatment was known to have been incomplete due to the proximity of the ectopic kidney, and when symptoms recurred, a hysterectomy was considered to be the treatment of choice.

Although the mixed and irregular echoes reported by ultrasound at the time of follow-up were often interpreted as scar tissue, histological examination, when available, usually indicated that healing had taken place in the absence of scar tissue and merely noted the presence of a little char and some giant cells. Obviously, too, when treatment was incomplete, some leiomyoma tissue was in evidence, but, here again, scar tissue was found to be absent on histological examination.

Finally, it must be noted that in the 30 cases examined by Tru-cut biopsies or following hysterectomy by immunohistochemical staining, specifically for the purpose of studying oestrogen receptors of which there are many in leiomyomas, invariably none was found after LITT had been performed. Likewise in the examination of such specimens by immunohistochemical staining for the identification of the epidermal growth factor, this was also found to be absent.

## DISCUSSION

Hysterectomy or myomectomy, if fertility is in question, has been the method of treating symptomatic uterine leiomyomas since gynaecologists first started opening the abdomen for treatment of this condition. Nevertheless, these operations are still associated with a significant mortality and morbidity. Many thousands of hysterectomies and myomectomies are carried out annually throughout the world and even in advanced countries the mortality rate is between 12 and 16 per 10,000 cases [23]. In the United States alone, more than 300 deaths occur annually from hysterectomy for benign conditions [24] and where injury to the bladder occurs in between 0.3–0.8% of cases, ureteric injury in 0.1–0.5%, bowel injury in 0.1% of cases and pulmonary embolus in 0.2–0.3% of cases [25]. In myomectomy, of course, haemorrhage frequently occurs and the wise surgeon usually obtains consent for hysterectomy should haemorrhage become life-threatening. Ureteric injury, also, is all too common when the gynaecologist is faced with much difficult dissection due to the presence of large broad ligament leiomyomas. For these and other

reasons, therefore, not least the cost of a hospital bed, the time off work, the loss of earnings, and risk of redundancy, some gynaecologists have been encouraged to seek alternative methods of treatment.

Endoscopic surgeons have for a number of years removed small or medium-size myomas by operative laparoscopy or hysteroscopy, but haemorrhage and adhesion formation can still occur, uterine rupture in subsequent pregnancy is not unknown [26], and large leiomyomas or intramural ones still defy the endoscopist's skill. For these reasons interstitial hyperthermia with the diathermy electrode was first tried [8,27,28], but since diathermy machines are arbitrarily calibrated [29], results were not necessarily reproducible so this has now been superseded by LITT.

Laser-induced interstitial thermotherapy has now been used for the treatment of >300 patients with uterine leiomyomas during the last 6 years with very satisfactory results. Following this treatment, leiomyomas of 6 cm or less usually disappeared within 6 months, but larger ones often needed to be treated twice. Oestrogen receptors and the epidermal growth factor were found to be invariably destroyed. Healing appeared to occur without the formation of scar tissue, but the presence of giant cells at the site of treatment suggested that they were involved in the removal of coagulated tissue. In a few cases some myoma tissue remained, but further growth did not occur under the influence of pregnancy or HRT treatment, which was in keeping with the observed destruction of the oestrogen receptors and epidermal growth factor.

No serious complications have occurred in the 300 patients treated to date, and all were treated as day surgical cases. The six hysterectomies reported were all performed months or years later and were in no way associated with the primary operation.

All the literature on the treatment of tumours by LITT indicate that the laser fibre or fibres are arranged at or around the centre of the tumour, whereas the author's research suggests that the fibres should be arranged around the periphery for if the blood vessels entering the tumour are destroyed, then the tumour will die from tissue anoxia. Perhaps if this method were employed, treatment of malignant tumours by LITT would be curative rather than palliative.

It is necessary also to point out that different tissues differ in composition and consistency. Indeed, certain similar tissues also differ, and this is

particularly true of uterine leiomyomas, which may vary between being soft and vascular or being hard and calcified. It follows, therefore, that the number of Joules necessary to produce a given effect in a certain organ cannot be reproduced in the tissue of a different organ. Indeed, in such tumours as uterine leiomyomas, where consistency may vary considerably, equivalent amounts of laser energy will not necessarily produce identical effects. This is because the amount of water, haemoglobin, fat, calcium, etc., all influence the transmission of the laser energy. Thus in arranging for the transmission of laser light into an organ or tumour for the purpose of raising the temperature sufficiently to cause coagulation and cell death, but not so high that immediate necrosis occurs, the photothermal interaction with the physical characteristics of the tissue need to be considered in addition to the technical aspect of constructing a practical laser machine. In other words, the ideal computerised laser machine for LITT would be fitted with a fibre splitter and multiple sensitized diffuser fibres small enough to pass through 15 gauge needles, which can be used percutaneously. Such sensitized fibres would be able to assess the physical nature of the tissue and the amount of absorption and scatter and so cut out when the required amount of laser energy had been used.

Finally, although the literature indicates that LITT produces tissue denaturation necrosis that heals by scarring and that occasionally severe necrosis and, rarely, abscess formation occur, nevertheless, this has not been the author's experience in the treatment of >950 leiomyomas in the course of 6 years. A gynaecologist is particularly conscious of the severe pain engendered by the development of red degeneration of a leiomyoma or torsion of a pedunculated myoma. Provided the correct low power and appropriate energy are used in the treatment of the specific tumour and the surrounding healthy tissue is undamaged, then pain is minimal and healing occurs without scarring. The body apparently slowly metabolizes and eliminates the coagulated tissue, and the only aid to this process that has, so far, been noted are the collection of giant cells at the site of treatment. This surely is an entirely new physical phenomenon that needs further study.

## CONCLUSIONS

The 300 patients reported in this series indicate that an alternative to hysterectomy or myo-

mectomy for the treatment of uterine leiomyomas is available, which, in the hands of an experienced video-laparoscopist, is safe and leaves the uterus capable of child bearing. It has progressed beyond the stage of being a research project, and a multicentre trial should enable other gynaecological laser surgeons to assess the veracity of the previous statement.

Lasers of different wavelengths are still being developed, so it may be that a future laser will produce even better results. Imaging facilities such as MRI are also being used and improved so a stage may eventually be reached when such tumours can be treated percutaneously by an imaging technique that is as good as direct vision.

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